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WASHINGTON, DC 20007			1646		
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Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	10/700,314	GUEGLER ET AL.				
Office Action Summary	Examiner	Art Unit				
	Prema M. Mertz	1646				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
 Responsive to communication(s) filed on <u>25 August 2006</u>. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. 						
Disposition of Claims						
4) ☐ Claim(s) 63-77 is/are pending in the applicatio 4a) Of the above claim(s) 70 and 71 is/are with 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 63-69, 72-77 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	drawn from consideration.					
9) The specification is objected to by the Examine	er.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/25/2006.	4) Interview Summan Paper No(s)/Mail D 5) Notice of Informal I 6) Other:	Date				

Application/Control Number: 10/700,314 Page 2

Art Unit: 1646

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/2006 has been entered.

- 2. Amended claims 63, 67-68, 75-77 (8/25/2006), and original claims 64-66, 69, 72-74, are under consideration by the Examiner.
- 3. Receipt of applicant's arguments and amendments filed on 8/25/2006 is acknowledged.
- 4. The following previous objections and rejections are withdrawn in light of applicants amendments filed on 8/25/2006:
- (i) the rejection of claims 63-69, 72-77 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,692,920 ('920) because the terminal disclaimer was filed and approved on 7/26/2006; and
- (ii) the rejection of claims 63-69, 72-77, under 35 U.S.C. 112, second paragraph, for the recitation of "including" and for the recitation of "hybridizes under stringent conditions".

Applicant's arguments with respect to the 35 U.S.C. 112, second paragraph rejection over claims 63, 67, 76-77 have been considered but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments filed on 8/25/2006 have been fully considered and were persuasive in part. The issues remaining and new issues are restated below.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph

7a. Claim 77 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 77 recites "under stringent conditions comprising washing at 68C in a solution of 0.2 x SSC and 0.1% SDS," which language is new matter in the claim, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

In the specification page 7, discloses:

"Although nucleotide sequences which encode ADEC and/or ADEC variants are preferably capable of hybridizing to the nucleotide sequence of the naturally occurring ADEC gene under stringent conditions, it may be advantageous to produce nucleotide sequences encoding ADEC or ADEC derivatives possessing a substantially different codon usage."

The specification does not disclose the specific limitations of "under stringent conditions comprising washing at 68C in a solution of 0.2 x SSC and 0.1% SDS" as recited in the claim 77. This rejection can only be obviated by reciting the specific washing conditions for which there is support in the instant specification.

Applicants argue that on page 6, lines 4-19, of the specification, the Sambrook et al. laboratory manual is incorporated by reference. However, contrary to Applicants arguments, the

Art Unit: 1646

Sambrook et al. laboratory manual is incorporated only with reference to the preparation and labeling of probes and not with respect to stringency of washing conditions.

7b. Claims 63-69, 72-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (10/13/2005) and for reasons of record set forth at pages 3-4 of the previous Office action (4/26/2006).

Applicants argue that claim 63 has been amended to omit recitation of "fragment of SEQ ID NO:2 and the claim has also been amended to recite a select group of variants which include: "(i) a conservative amino acid substitution in SEQ ID NO:2;

- (ii) an insertion of from 1-5 amino acids in SEQ ID N0:2; and
- (iii) a deletion of from 1-5 amino acids in SEQ ID N0:2."

Applicants also argue that claim 63 recites that the polypeptide has chemotactic activity or activates neutrophils or monocytes. However, contrary to Applicants arguments except for an antibody to a polypeptide of amino acid sequence set forth in SEQ ID NO:2, Applicants have failed to provide a written description for any other antibody. In the decision of *The Regents of the*

University of Calfornia v. Eli Lilly and Company, 43 USPQ2d 1398 (CAFC 1997), the court held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor

invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997), *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" (T)he description must clearly allow persons of ordinary skill in the art to recognize that (the inventor) invented what is claimed). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the instant application, there is a complete lack of written description for an antibody to a polypeptide of amino acid sequence anything less than the amino acid sequence set forth in SEQ ID NO:2. Applicants assert that because SEQ ID NO:2 includes 109 amino acids, the "substitution", "insertion" or "deletion" recited in claim 63 would result in a polypeptide that has greater than 95% sequence identity to SEQ D NO:2. However, contrary to Applicants assertion, The Examiner is relying on the following decisions: *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co.*, CAFC (03-1304) decided February 13, 2004 and *Noelle v. Lederman*, decided January 20, 2004, to demonstrate that Applicants have failed to demonstrate or provide evidence of possession of the invention.

In *University of Rochester v. G.D. Searle & Co.*, a patent directed to method for inhibiting prostaglandin synthesis in human host using an unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing activity of enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since the invention consisted of performing "assays" to screen

compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of invention, or provide information such that one skilled in art could identify suitable compound. And since the specification did not indicate that the compounds were available in a public depository, the claimed treatment method could not be practiced without the compound. The written description requirement must still be met in some way so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed." *Enzo*, 323 F.3d at 968. The Court further explained that:

[T]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. . . . A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its function of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. [Regents of the Univ. of Cal. v.] Eli Lilly [& Co., Inc.], 119 F.3d [1559,] 1568 [(Fed. Cir. 1997) ("Lilly")] The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Id.

Enzo, 323 F.3d at 968.

Thus, the Court in *University of Rochester* held that the inventors could not be said to have "possessed" the claimed invention without knowing of a compound or method certain to produce the compound. Thus, the patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic a class of compounds defined only by their desired properties.

Therefore, similar to *University of Rochester*, here, the full breadth of the claims fails to meet the written description provision of 35 U.S.C. §112, first paragraph.

In the *Noelle* case, the claims in the Noelle application were directed to the genus, murine, chimeric, humanized and human forms of CD40CR monoclonal antibody. An

interference was set up between the Noelle application and the Lederman patent 5,474,771, which claimed the human form of CD40CR monoclonal antibody. The Court concluded that the Board made a detailed analysis of this court's precedent pertaining to the doctrine of written description, focusing on the holding from Regents of the University of California v. Eli Lilly & Co. that an "adequate written description of a DNA sequence claim requires a precise definition, such as structure, formula, chemical name, or physical properties." 119 F.3d 1559, 1566 (Fed. Cir. 1997). The Board analogized the DNA claims from Regents to the antibodies in Noelle's application. Accordingly, the Board held that Noelle's claims regarding the genus and human claims from the 08/742,480 application lacked written description support in the specification of Noelle's earlier 07/835,799 application because Noelle failed to describe any structural features of the human or genus antibodies or antigens. In other words, the Board found that the claims covering the genus and human antibodies constituted new matter because they lacked adequate written description in Noelle's earlier '799 application. The Board did not reject the claims, but rather denied them the benefit of the earlier filing date of Noelle '799.

The Court in Noelle held that the written description requirement has been defined many times by the court, but perhaps most clearly in <u>Vas-Cath</u>. The court held as follows:

35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

<u>Vas-Cath</u>, 935 F.2d at 1563-64 (emphasis in original). Thus, the test to determine if an application is to receive the benefit of an earlier filed application is whether a person of ordinary

skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application. An earlier application that describes later-claimed genetic material only by a statement of function or result may be insufficient to meet the written description requirement. See Regents, 119 F.3d at 1566. This court has held that a description of DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. (quoting Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir. 1993)). Therefore, this court has held that statements in the specification describing the functional characteristics of a DNA molecule or methods of its isolation do not adequately describe a particular claimed DNA sequence. Instead "an adequate written description of DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1566-67 (quoting Fiers, 984 F.2d at 1171).

Indeed, the court in Enzo Biochem v. Gen-Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) ("Enzo Biochem II"), stated that "the written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." Also, the court held that one might comply with the written description requirement by depositing the biological material with a public depository such as the American Type Culture Collection ("ATCC"). Id. at 970. The court proffered an example of an invention successfully described by its functional characteristics. The court stated:

For example, the PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the

Art Unit: 1646

functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.

Id. The court adopted the USPTO Guidelines as persuasive authority for the proposition that a claim directed to "any antibody, which is capable of binding to antigen X" would have sufficient support in a written description that disclosed "fully characterized antigens." Synopsis of Application of Written Description Guidelines, at 60, available at http://www.uspto.gov/web/menu/written.pdf (last visited Jan. 16, 2003) (emphasis added).

Therefore, based on past precedent, the Court in *Noelle* concluded that as long as an applicant has disclosed a "<u>fully characterized</u> antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

Therefore, the CAFC decisions in *Noelle* and *University of Rochester* are controlling precedents for the claims in the instant case and it is suggested that Applicant visit these decisions. Contrary to Applicant's arguments, there is absolutely no written description for the claimed subject matter drawn to an antibody to a variant of SEQ ID NO:2 as recited in claim 63 and an antibody to a polypeptide variant encoded by a polynucleotide that hybridizes to a complement of SEQ ID NO:1 under the conditions recited in claim 77(b).

Therefore, Applicants were not in possession of the claimed antibodies.

7c. Claims 63-69, 72-77, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody which specifically binds a protein consisting of the amino acid sequence set forth in SEQ ID NO:2 does not reasonably provide

Art Unit: 1646

enablement for an isolated antibody to a polypeptide variant of SEQ ID NO:2 as recited in claim 63 or a polypeptide variant as recited in claim 77(b). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 7-10 of the previous Office action (10/13/2005) and for reasons of record set forth at pages 4-5 of the previous Office action (4/26/2006).

Applicants argue that claim 63 has been amended to recite a select group of variants, claim 77 has been amended to recite specific "stringent conditions" for hybridization, the specification provides methods for determination of ADEC-induced chemotaxis or cell activation and therefore one of skill in the art has a method for testing the recited subject matter. However, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) and Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988) (which has been cited by Applicants. If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. Applicants

Art Unit: 1646

arguments that the standard is that of mutating a subject protein and testing to see if it retains the desired biological activity (in this case, chemotactic activity) is a position that has been routinely dismissed by the courts, as shown by the decisions cited above.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing an antibody to a variant of SEQ ID NO:2 as recited in claims 63 and 77. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner. It is this additional characterization of the disclosed protein that is required in order to obtain the functional and structural data needed to permit one to produce an antibody to a protein of SEQ ID NO:2, which meets both the structural and functional requirements of the instant claims that constitutes undue experimentation.

Furthermore, Applicant is encouraged to review the discussion of 35 U.S.C. § 112, first paragraph, in a recent CAFC decision, Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein and recombinant DNA issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial

Application/Control Number: 10/700,314 Page 12

Art Unit: 1646

interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims. In the instant case it is highly improbable that an antibody to a protein variant of SEQ ID NO:2 will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to predictably alter the sequence of SEQ ID NO:2 with any reasonable expectation that the resulting protein will have the desirable characteristics.

Furthermore, with respect to the rejection of claims 63 and 77, Applicants argue that the teachings of the present application, especially when taken together with the knowledge of one of ordinary skill in the pertinent art, provide an enabling disclosure for present claims 63 and 77. This is not adequate guidance as to the nature of the analogues or variants of SEQ ID NO:2 that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Furthermore, the claim does not indicate the number of conservative substitutions i.e. there is no upper limit to the amount of substitutions. Therefore Applicants have not presented enablement commensurate in scope with the claims.

Claim rejections-35 USC § 112, second paragraph

Art Unit: 1646

8. Claims 63-69, 72-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 is vague and indefinite for several reasons.

Claim 63, sub-part (b)(ii)-(iii) recites "of from 1-5 amino acids" which is vague and indefinite because it is unclear whether these 1-5 amino acids are contiguous or non-contiguous.

Claims 63, 67-68, 75-77, are vague and indefinite because they recite "or other antigenspecific binding molecule". It is unclear what the metes and bounds of this term are. Applicants argue that a definition of this term is provided in the specification at page 10, lines 28-33. However, contrary to Applicants arguments, the specification on page 10, lines 28-33, recite "synthetic antibodies or other specific-binding molecules", however, these is no definition for "specific-binding molecules" in the instant specification.

Claims 64-66, 69, 72-74, are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

Claim Rejections - 35 USC § 102

9. Claims 63-67, 76-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al.(US Patent No. 6,174,995).

This rejection is maintained for reasons of record set forth at page 6 of the previous Office action (4/26/2006).

Applicants argue that Li does not teach a polypeptide of SEQ ID NO:2 as recited in the rejected claims and that a BLAST alignment of SEQ ID NO:2 and MCP-4 indicates that the two proteins have 33% sequence identity within a portion of SEQ ID NO:2 from amino acids 60-95

Art Unit: 1646

and within a portion of MCP-4 from amino acids 53-93. However, contrary to Applicants arguments, what is being claimed in the instant case is an antibody to a variant of SEQ ID NO:2 or an antibody to a variant of SEQ ID NO:2 which is encoded by a polynucleotide that hybridizes to a complement of SEQ ID NO:1 under the conditions recited in claim 77(b). Furthermore, contrary to Applicants arguments, a polypeptide of SEQ ID NO:2 is not being claimed in the instant application. Applicants acknowledge that the protein of Li et al. recognizably shares regions of sequence identity with Applicants protein of amino acid sequence set forth in SEQ ID NO:2. The Examiner has provided evidence and established that the antibody of the prior art would bind to the instant protein of amino acid sequence set forth in SEQ ID NO:2 due to the presence of homologous sequences in each protein in which there are stretches of 6 or more amino acids that are identical between the protein of the prior art and the instant protein. Since the office does not have a laboratory to test the reference antibodies, it is Applicants burden to show that the reference antibodies do not bind to the claimed SEQ ID NO:2.

Claim Rejections - 35 USC § 103

10. Claims 63, 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al.(US Patent No. 6,174,995) as applied to claims 63-67, 76-77 above, and further in view of Hart (U.S. Patent No. 5,094,941).

This rejection is maintained for reasons of record set forth at pages 6-7 of the previous Office action (4/26/2006).

Applicants argue that Li does not teach a polypeptide or polynucleotide as recited in the rejections claims and therefore Li does not render the claimed subject matter obvious.

Application/Control Number: 10/700,314 Page 15

Art Unit: 1646

Applicants are absolutely right. Li does not teach or suggest a polypeptide or polynucleotide as recited in the rejected claims. However, Li teaches an antibody to MCP-4 and since MCP-4 and the instant polypeptide have regions of 6 amino acids in common, an antibody to MCP-4 would have the inherent property of binding to the protein of SEQ ID NO:2 of the instant application.

Conclusion

No claim is allowed.

Claims 63-69, 72-77 are rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz Ph.D., J.D. Primary Examiner Art Unit 1646 September 26, 2006